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FISCAL IMPACT STATEMENT

LS 6848
BILL NUMBER: SB 272

NOTE PREPARED: Apr 15, 2013
BILL AMENDED: Apr 11, 2013

SUBJECT: Prescription Products.

FIRST AUTHOR: Sen. Miller Patricia
FIRST SPONSOR: Rep. Clere

BILL STATUS: As Passed House

FUNDS AFFECTED: X **GENERAL**
DEDICATED
FEDERAL

IMPACT: State

Summary of Legislation: This bill has the following provisions:

(1) Allows a pharmacist to substitute an interchangeable biosimilar product for a prescribed biological product if certain conditions are met.
(2) Requires the Board of Pharmacy to maintain an Internet web site that lists the biosimilar biological products that are determined to be interchangeable.
(3) Allows the Board of Pharmacy to adopt rules.
(4) Provides that a written or electronic prescription for a biological product must comply with the existing prescription form requirements.
(5) Requires, during the 2013 legislative interim:
(A) the Division of Mental Health and Addiction (DMHA) to provide the Health Finance Commission with specified information concerning opioid treatment programs; and
(B) the Health Finance Commission to study how Indiana law may affect prescribing and substituting of biosimilar biological products.

Effective Date: (Amended) July 1, 2013.

Explanation of State Expenditures: *Summary*: This bill could increase the workload of the Indiana Professional Licensing Agency (PLA) to maintain the required web pages. Increases in workload are expected to be minimal, and the PLA reports this requirement can be accomplished within the level of resources currently available to the agency.

Additionally, the bill specifies study topics for the Health Finance Commission and requires the DMHA and the PLA to provide specific information to the Health Finance Commission during the 2013 interim. This provision is not expected to have a fiscal impact since a study of these topics could be conducted by the existing Health Finance Commission, provided the study of these topics does not result in any additional meetings of the Commission that would not have occurred anyway.

Additional Information:

Health Finance Commission: Currently, pharmacists are required to report the following information to the INSPECT program when dispensing opioids (IC 35-48-7-8.1):

(1) The patient's name.
(2) The patient's date of birth.
(3) The National Drug Code number of the dispensed controlled substance.
(4) The date the controlled substance was dispensed.
(5) The quantity of the dispensed controlled substance.
(6) The U.S. Drug Enforcement Agency registration number of the dispenser/prescriber.
(7) Other data required by the program.

The bill would require the PLA to, during the 2013 interim, report to the Health Finance Commission the impact of implementing a program where OTP staff who administer opioids report the same information currently required of pharmacists who dispense opioids to INSPECT.

The bill also specifies that during the 2013 interim, the Health Finance Commission is to study (1) how Indiana law may affect the prescription of biosimilar biological products and (2) the use of methadone and opioids in treatment programs and clinical settings. This requirement is expected to have no fiscal impact.

Additionally, the bill requires the DMHA to provide certain information to the Health Finance Commission by September 1, 2013. This requirement will increase the workload of the DMHA, but this requirement is expected to be fulfilled with existing staffing and resources.

Biosimilar Biological Products: Current Indiana law provides for the substitution of generic drugs for brand name drugs but does not provide for the substitution of the new biotech drugs defined as biological products. The bill defines biological products, biosimilar products, and interchangeable biosimilar products. The bill allows for the substitution of interchangeable biosimilar products for the biological products by a pharmacist so long as the prescriber is notified of the substitution within five days. Biological products (brand names) are currently sold in the U.S. A few copies or biosimilar products are sold in Europe, but these are not yet available within the U.S. The Food and Drug Administration is currently working on rules for introducing biosimilars - defining a process different from that for generic drugs to demonstrate the safety, efficacy, and interchangeability of biosimilar products. Currently, there are no biosimilar interchangeable drugs available on the U.S. market.

Explanation of State Revenues:

Explanation of Local Expenditures:

Explanation of Local Revenues:

State Agencies Affected: DMHA, Board of Pharmacy, PLA.

Local Agencies Affected:

Information Sources: Christina Hage, FSSA; Marty Allain, PLA.

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